UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/641,701 | 08/21/2000 | Yoshinao Kojima | 195870USO | 8831 |

22850 7590 02/13/2003

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

| EXAMINER | |
|---|---|
| PROUTY, REBECCA E | |
| **ART UNIT** | **PAPER NUMBER** |
| 1652 | |

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/641,701 | Kojima et al. |
| **Examiner** | **Art Unit** |
| Rebecca Prouty | 1652 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Nov 19, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *12-35* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *12, 18, 24, and 30* is/are allowed.

6) ☒ Claim(s) *13-17, 19-23, 25-29, and 31-35* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-11 have been canceled. Newly presented claims 12-35 are at issue and are present for examination.

Applicants' arguments filed on 11-19-02, paper No. 13, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

It is noted that the examiner spoke with Daniel Pereira on 12/11/02 with regard to an examiner's amendment which would have put the claims in condition for allowance which was approved. However, this amendment has not been made as a new piece of prior art which would apply to the claims even as they were to be amended was identified following the date of the interview. As such the claims remain as they were presented in the amendment of 11-19-02. The following amendments to the claims (which were to be made in the proposed examiner's amendment)are still suggested and would overcome all rejections herein under 35 U.S.C. 112:

In Claim 13, insert --hybridization in 50% formamide, 4X SSC, 50 mM HEPES (pH 7.0), 10X Denhardt's solution, and 100 $\mu$g/$\mu$l salmon sperm DNA at 42 °C,-- after --wherein the stringent conditions comprise--.

In Claim 14, --replace --with an amino acid sequence in SEQ ID NO:2-- with --fragment of SEQ ID NO:2 having an activity to

transfer a galactose residue from a galactose donor to a C4 position of a galactose residue in lactosylceramide or galactosylceramide--.

In Claims 15-17, replace --Claim 12-- with --Claim 14--.

Claim 13 is objected to because of the following informalities: 50° should be 50 °C. Appropriate correction is required.

Claims 13, 15-17, 19, 21-23, 25, 27-29, 31 and 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13, (upon which Claims 19, 25, and 31 depend) is confusing in the recitation of "wherein the stringent conditions comprise washing in 2X SSC and 0.1% SDS at room temperature, and washing in 0.1X SSC and 0.1% SDS at a temperature of 50° or less" as the recited wash conditions (which were taken from page 16 of the specification as previously suggested) are clearly non-stringent washes. While as discussed previously, the meaning of the term "stringent" is vague in the art, the recited wash conditions would never be considered stringent. As such, the recitation of them as defining "stringent conditions" is confusing. It is noted that applicants omitted the inclusion of

the conditions of the actual hybridization recited on page 16 which are within the scope of conditions that an ordinary artisan might consider to be stringent. Inclusion of these conditions (as recited above) is suggested.

Claim 15 (upon which Claims 21, 27, and 33 depend) are indefinite and unclear in the recitation of "The DNA of Claim 12, consisting essentially of nucleotides 269 to 1192 of SEQ ID NO:1" as any DNA within the scope of Claim 12 must in view of the limitations of Claim 12 comprise all of SEQ ID NO:1. Therefore smaller fragments of SEQ ID NO:1 (such as 269-1192 which Claim 15 appears to intend to encompass) are outside the scope of a DNA of Claim 12 (as is recited in Claim 15). Therefore Claim 15 is either not further limiting of Claim 12 or confusing in reciting limitations that are mutually exclusive. Claims 16 and 17 (upon which Claims 22-23, 28-29, and 334-35 depend) are similarly either not further limiting of Claim 12 or confusing in reciting limitations that are mutually exclusive. For the purposes of examination Claims 15-17 are examined as if they were written as independent claims i.e., Claim 15 has been examined is if it recited "An isolated DNA consisting essentially of nucleotides 269 to 1192 of SEQ ID NO:1".

Claims 14, 20, 26 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of DNA molecules which encode a polypeptide with an amino acid sequence **in** SEQ ID NO:2 and which are 1975 nucleotides of less in length. As the claims does not limit the size of the encoded fragment of SEQ ID NO:2 in any way these claims recite any DNA of 1975 nucleotides or less that encode a single amino acid.

The specification does not contain any disclosure of the function of all DNA sequences of 1975 nucleotides or less that encode a single amino acid. The genus of DNAs that comprise these above DNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a few species of the claimed genus (i.e., SEQ ID NO:1, nucleotides 269-1192 of SEQ ID NO:1, nucleotides 191-1192 of SEQ ID NO:1 and nucleotides 134-1192 of SEQ ID NO:1) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that

the applicant had possession of the claimed invention at the time the instant application was filed. See suggested amendment above for language which would overcome this rejection.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 13, 14, 19, 20, 25, 26, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNAs encoding a Gb3 synthase which will hybridize to SEQ ID NO:1 under the conditions described on page 16, lines 1-3, does not reasonably provide enablement for any DNA encoding a GB3 synthase which will hybridize to SEQ ID NO:1 under the non-stringent wash conditions recited in Claim 13, nor for any DNA of 1975 nucleotides or less that encode a single amino acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection is explained in the previous Office Action.

Applicants appear to believe that the amendments to the claims would overcome the instant rejection however, this is not the case for claims 13 and 14 (and the claims which depend

therefrom) as the scope of Claim 13, remains to encompass any polynucleotide encoding a Gb3 synthase which is about 1975 nucleotides in length as any polynucleotide will hybridize to SEQ ID NO:1 under the non-stringent was conditions recited in Claim 13. Furthermore as previously stated Claim 14 recites a genus of DNA molecules which encode a polypeptide with an amino acid sequence **in** SEQ ID NO:2 and which are 1975 nucleotides of less in length. As the claim does not limit the size of the encoded fragment of SEQ ID NO:2 in any way this claim and those which depend therefrom recite any DNA of 1975 nucleotides or less that encode a single amino acid. For the reasons previously presented, the specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international

application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-17 are rejected under 35 U.S.C. 102(a) as being anticipated by McClaren (GenBank entry Z82176).

McClaren teach a human clone comprising sequence (bases 30258-32135 of McClaren) 100% identical to the complement of nucleotides 87-1964 of SEQ ID NO:1 and thus encoding all of SEQ ID NO:2. Therefore the nucleic acid of McClaren clearly comprises all of nucleotides 269-1192, 191-1192 or 134-1192 of SEQ ID NO:1. As stated in MPEP 2111.03, "for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are (of the recited fragments of SEQ ID NO:1 in the instant case), "consisting essentially of" will be construed as equivalent to "comprising." As such the nucleic acid of McClaren anticipates claims 15-17. See suggested amendments above for amendments to the claims which would overcome the instant rejection.

Claims 14, 20, 26 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. (WO 01/57190).

Tang et al. teach a polynucleotide (SEQ ID NOS: 514 and 2482 consisting of the full length and coding portion of the same gene) and the encoded protein (SEQ ID NO:3466) thereof as well as

vectors and host cells comprising said polynucleotide and methods of expressing the encoded protein. SEQ ID NO:2482 was first disclosed as SEQ ID NO:6712 of US priority application 09/496,914 (see particularly Table 5, page 205 of Tang et al.) and is 100% identical to nucleotides 134-1192 of SEQ ID NO:1 with the exception of a single degenerate mismatch at position 1120. As such the effective filing date of Tang et al. for the subject matter of SEQ ID NO:2482 is 2/3/00 and Tang et al. anticipate the current claims. Applicants should note that if the claims were amended as in the examiner's amendment which was proposed, Tang et al. would anticipate the same claims. Claims 15-17 are not anticipated in view of the single mismatch at position 1120 and Claim 13 is not anticipated as SEQ ID NO:2482 of Tang is only 1111 nucleotides in length and thus does not meet the limitation of Claim 13 of "about 1975 nucleotides". However, Tang et al. would anticipate a claim to any polynucleotide encoding SEQ ID NO:2 or the specific fragments thereof of amino acids 20-353 or 46-353 thereof.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

> skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 19, 25, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang et al. (WO 01/57190) in view of Tsein et al. (US Patent 5,625,048).

Tang et al. is discussed above. SEQ ID NO:2482 of Tang et al. meets all limitation of Claim 13 except it is only 1111 nucleotides in length and thus Tang et al. does not specifically disclose a polynucleotide of about 1975 nucleotides in length as recited in Claim 13. However Tang et al. do disclose that the polynucleotides disclosed can be fused to other polynucleotides to produce fusion proteins (see page 32).

Tsein et al. teach polynucleotides encoding *Aequorea* GFP which is a commonly used fusion partner in the art as it can be easily tracked and quantified as well as polynucleotides encoding such fusion polypeptides. (see particularly column 6 and Claims 15-17 and 23-25). Tsein et al. further teach the inclusion of

sequences encoding additional small peptide sequences such as a His tag and/or a flexible peptide spacer between the sequences encoding GFP and the peptide of interest. The polynucleotide sequence encoding GFP is 716 nucleotides in length.

Therefore, it would have been obvious to one of skill in the art to fuse the sequence encoding SEQ ID NO:2482 of Tang et al. to the sequence encoding GFP and optionally including nucleotide sequences encoding a histidine tag, an oligopeptide spacer and/or a promoter sequence for the expression of the fusion protein. All such constructs would be within the scope of "about 1975" nucleotides in length and would clearly hybridize under even highly stringent conditions to SEQ ID NO:1 and encode a Gb3 synthase. One would have been motivated to do so for the ease of detecting g and purifying the protein encoded by SEQ ID NO:2482 of Tang et al.

Claims 12, 18, 24, and 30 are allowed. The prior art does not teach any polynucleotide comprising all of SEQ ID NO:1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rebecca Prouty
Primary Examiner
Art Unit 1652